Lessons Learned and Revisions under Consideration for APHIS' Biotechnology Framework

Under the authority of the Plant Protection Act (PPA), the U.S. Department of Agriculture (USDA) regulates the importation, interstate movement, and field testing of genetically engineered (GE) organisms that may pose a plant health risk. USDA's Animal and Plant Health Inspection Service (APHIS) works in partnership with the U.S. Food and Drug Administration and the U.S. Environmental Protection Agency to ensure that the development, testing, and use of the products of biotechnology occur in a manner that is safe for plant and animal health, human health, and the environment.

APHIS continually works to ensure that its regulatory oversight is effective, science-based, and current with the latest scientific developments. While preparing the *Report of LibertyLink Rice Incidents*, APHIS took the opportunity to review lessons learned both from its LibertyLink investigation and from its 20 years of experience in the regulation of biotechnology. The review took place in the context of APHIS' current initiative to explore revisions to its biotechnology regulations in Title 7, Part 340 of the *Code of Federal Regulations* (CFR). In July 2007, APHIS published a draft environmental impact statement (http://www.aphis.usda.gov/newsroom/content/2007/07/content/printable/complete_eis.pdf) that evaluates potential options for revising the biotechnology regulatory program. These options are aimed at maintaining proper oversight of GE organisms based on evaluation of risk and the current science as the technology advances. As a result of this review, APHIS has compiled a list of lessons learned and considerations to enhance its regulatory framework. These include:

Quality and completeness of records. Records are sometimes not easily obtainable because they might not be retained by the permit and notification holders. (Notifications are an administratively streamlined alternative to permits.) As a consequence, APHIS has sometimes found that the quality and completeness of information obtained during investigations is not optimal. This makes it difficult to conduct thorough and timely investigations.

APHIS is exploring whether to require the creation and retention of additional records to inform potential investigations. Currently there are few requirements for record retention in 7 CFR 340. APHIS is also considering whether additional recordkeeping requirements should be established prior to any revision to the regulations to support investigative work.

Availability of representative samples. In the rice investigation, the effort to test seed was hampered by the unavailability of representative seed samples. The PPA does not provide APHIS with the authority to subpoena anything other than documents in its investigations. Samples of physical evidence—including tissue, seed, or other plant parts—have only been obtained through voluntary submission to APHIS. This has sometimes resulted in delays.

APHIS is considering alternatives that would allow the Agency to obtain necessary physical evidence in an expedient manner and without unnecessary delays. These alternatives include: 1) Exploring revisions to the PPA to provide APHIS the authority to subpoena physical evidence for the purpose of investigation; and 2) Revising 7 CFR 340 to require that representative samples of events introduced must be retained by permit and notification holders for a designated period of time. The objective of these alternatives would be to hold samples in a way that allows for molecular testing. To that end, APHIS is considering to convene an expert advisory panel to explore how to implement this requirement in a way that is scientifically sound but not an obstacle to research and development.

Maintaining identity and control in the event of an unauthorized release. In some investigations, APHIS found that researchers or developers were unclear about their responsibilities in the event of an unauthorized release and had not fully considered the consequences or measures that they should take in such an event. As a result, APHIS could not obtain evidence from the researchers or developers indicating how they would regain identity and control of regulated material if either became lost. Consequently, APHIS had to rely on the chance availability of some information and capabilities that the applicant had.

APHIS is considering whether to revise 7 CFR 340 to address this issue. Among the considerations are requiring that the applicant submit a contingency plan with their permit application that addresses the unauthorized release of regulated articles to include dispersal, commingling, and persistence due to climate, animal incursion, or human error. APHIS is also considering whether to require permit holders: 1) to have gene-specific testing procedures needed to identify regulated articles in the event of an unauthorized release; and 2) to maintain an appropriate sample of the regulated articles for use as a positive control for a designated period after the field release in the event that testing is necessary.

Corrective actions in the event of unauthorized releases. In some previous unauthorized releases, the Federal Government became responsible for determining corrective actions of a highly technical nature after an unauthorized intermixing of regulated materials with non-regulated materials. The time required to determine such actions can cause delays in the actual response. Researchers or developers have the greatest level of expertise with the plant line to identify measures that they can undertake to mitigate the effects of an unauthorized release.

APHIS is considering whether to revise 7 CFR 340 to address this issue. Among the alternatives under consideration is requiring applicants to submit a comprehensive, written corrective action plan for any incident in which viable regulated articles could persist in the environment or in the seed, food, or feed supply following an incident.

Conducting molecular forensics. During the rice investigation, the three USDA Marketing and Regulatory Programs (MRP) agencies—APHIS, AMS, and GIPSA—worked collaboratively to assure that the sampling and testing of all physical seed samples met scientifically sound sampling and testing protocols and legally sound evidence handling requirements, such as chain of custody. However, these efforts were complicated by lack of prior institutional awareness, links, and agreements.

MRP will develop an initiative to address future needs in the processing of plant tissue collected as evidence for molecular identification analysis. Similar concerns may be present for the analysis of insects, arthropods, fungi, and bacteria that are also subject to introduction through 7 CFR 340. An expert team from USDA will examine this topic in detail and make recommendations for resources, memoranda of understanding, agreements, and collaborations that would reduce the time and resources required to address any future testing and sampling events.

Contractual relationships. Investigations may be hindered by incomplete access to agreements that had been made among researchers or developers and other parties. In some cases, only oral agreements had been made, and in others contracts had expired or did not contain needed information to conduct a thorough and timely investigation.

APHIS is exploring revisions to 7 CFR 340 to require certain business agreements made among GE technology researchers or developers and other parties regarding regulated articles to be in writing. Such agreements could include the duration of the agreement, ownership of regulated materials, genetic events involved, and other items that may be deemed critical as BRS revises this regulation. APHIS is also considering whether to establish retention policies deemed critical to investigations.

Ensuring the use of the latest science for isolation as a confinement tool. During investigations, an issue that APHIS continues to consider is the sufficiency of isolation distances between experimental crops and nearby crop fields to ensure confinement of GE trials. As breeding techniques and GE technology continue to advance, it will be essential to incorporate the latest scientific information into APHIS' regulatory requirements to maximize confinement of regulated articles. For example, APHIS will need to use the latest scientific information on factors such as pollen flow to ensure that regulated GE material is sufficiently isolated from conventional breeding and seed production fields.

APHIS will continue to work with expert organizations such as the recent initiatives underway with the Association of Official Seed Certifying Agencies to gather and peer review scientific information regarding outcrossing and isolation distances for key crops. APHIS is exploring revising policy and guidance documents to ensure the latest science is incorporated into isolation distances and

to require minimum distances between seed breeding fields and GE variety development.

Importance of quality management systems to manage research effectively. APHIS recognizes that robust quality management systems are not consistently found throughout the biotechnology research and development community. Effective quality management systems may reduce the likelihood of compliance problems.

In September 2007, USDA announced a new program, BQMS, to help universities, small businesses, and large companies develop sound management practices. The goal of the voluntary program is to aid participants in establishing policies and practices that will enable them to proactively address potential compliance problems before they materialize. APHIS will conduct extensive outreach to all applicants to encourage widespread participation in the program.

Using ePermits to store important documents and other information related to the permit and notification processes. Difficulties in quickly retrieving information can create delays during inspections and investigations. The ability to electronically store all information associated with permits and notifications would expedite data retrieval and enhance the ability to respond to an incident.

APHIS will explore the capability of its ePermits system—currently used to capture information on permits and notifications—to conduct data mining to more quickly retrieve information that could be pertinent to an investigation. The ePermits database holds the promise of efficiently gathering many facts relevant to investigations, making the information readily available and tying it to other related investigative tools.